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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,127	10/16/2001	Steven Curtis Zicker	IR 6493-02	3786

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 01/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,127

Applicant(s)

ZICKER ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The following is responsive to Applicant's amendment received Sep. 16, 2002.

Claim 38 is cancelled. New claim 39 is added. Claims 1-37, 39 are currently pending.

1. Newly submitted claim 39 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 39 is directed to a distinct method of inhibiting the loss of learning ability or increasing the learning ability which requires a different mode of operation and different method steps. Furthermore, this claim raises different issues of patentability and would support separate patents.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 39 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The previous claims objections set forth in paragraphs 1-2 of the office action mailed May 7, 2002 **are withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claims rejections under 35 USC 112, paragraph 2 set forth in paragraphs 3-10 of the office action mailed May 7, 2002 **are withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous rejection of claim 38 under 35 USC 103(a), set forth in paragraph 20 of the office action mailed May 7, 2002 **is withdrawn** in view of Applicant's amendment cancelling claim 38.

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Additionally, since Applicant has not addressed, at this time, the double patenting/obviousness-type double patenting rejections set forth in paragraphs 21-24 of the office action mailed May 7, 2002, these rejections will be maintained for reasons already of record.

Applicant's arguments traversing the previous claims rejections under 35 USC 102(b); 102(e) and 35 USC 103(a) set forth in paragraphs 11-19 of the office action mailed May 7, 2002 have been considered but are not found to be persuasive.

Said rejections are maintained essentially for the reasons given previously in the office action mailed May 7, 2002, with the following additional comment:

Claim Rejection under 35 USC 102(b):

It is Applicant's position that Bernotavicz does not disclose a diet which anticipates the claimed invention. Instead there are combinations of unknown vitamins and minerals at unknown percents. Bernotavicz does not teach Applicant's claimed amounts of claims 1 and 37.

Said arguments have been considered but are not found to be persuasive.

It is respectfully submitted that Applicant is arguing (as well as claiming) the effective amounts **functionally**, i.e. an effective/sufficient amount of an antioxidant to Since Applicant is claiming amounts functionally, one of ordinary skill in the art must turn to the specification where, at pages 5-6, Applicant describes the amounts of antioxidants that should be present in the diet compositions. However, Applicant has not clearly argued how these amounts of antioxidant in the claimed invention are not disclosed or are distinguished over the amounts disclosed in the prior art. Applicant has not specifically argued, on the record, how the claimed

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amounts of antioxidant differ from the amounts of antioxidant in the prior art. The Examiner maintains that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Absent evidence and arguments to the contrary, the pet food diet containing the antioxidant(s) would be capable of inhibiting the mental deterioration or the mental capacity of an aged pet or increasing the mental capacity of the aged pet.

Claim Rejection under 35 USC 102(e):

It is essentially Applicant's position that Paluch fails to disclose a pet diet containing sufficient amounts of antioxidant to accomplish the functions of claims 1 and 37.

Said argument has been considered but is not found to be persuasive.

It is respectfully submitted that Applicant is arguing (as well as claiming) the effective amounts **functionally**, i.e. an effective/sufficient amount of an antioxidant to Since Applicant is claiming amounts functionally, one of ordinary skill in the art must turn to the specification where, at pages 5-6, Applicant describes the amounts of antioxidants that should be present in the diet compositions. However, Applicant has not clearly argued how these amounts of antioxidant in the claimed invention are not disclosed or are distinguished over the amounts disclosed in the prior art. Applicant has not specifically argued, on the record, how the claimed amounts of antioxidant differ from the amounts of antioxidant in the prior art. The Examiner

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maintains that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Absent evidence and arguments to the contrary, the pet food diet containing the antioxidant(s) would be capable of inhibiting the mental deterioration or the mental capacity of an aged pet or increasing the mental capacity of the aged pet.

In addressing the rejection under 35 USC 102(e) over Harper, Applicant argues that Harper cannot support such a rejection due to its breadth and vagueness. Specifically, Applicant argues that only one paragraph is related to the rejected claims and that Harper discloses numerous diseases or disorders which include aging. The Harper reference fails to teach the claimed invention which refers to deterioration of mental capacity.

Applicant's arguments are well noted; however, the Examiner respectfully maintains that Harper anticipates the claimed invention. Harper discloses cat or dog foodstuff which contain an antioxidant cocktail (vitamin A and C) useful for treating disorders such as aging and neurodegenerative diseases which are known to affect the mental capacity of a dog or cat. The Examiner respectfully maintains that the claims are anticipated by Harper because Harper discloses administration of identical antioxidants to a pet using Applicant's claimed methods steps. Accordingly, inhibiting the deterioration of the mental capacity of the pet and increasing the mental capacity of the pet are inherent.

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In addressing the previous claims rejection under 35 USC 102(e) over the Milgram et al. abstract, Applicant contends that no specific antioxidant is provided in the abstract. However, the rejected claims do not require a specific antioxidant but instead are broadly drawn to a pet diet having effective amounts of antioxidants. Therefore, the Examiner respectfully maintains that Milgram continues to anticipate the claimed invention.

Claim Rejection under 35 USC 103(a):

Concerning the previous 35 USC 103(a) rejection of claims 6, 7, 9-11, 12-36 (see paragraph 18 of the office action mailed May 7, 2002), it is Applicant's position that Sole refers to a normal dietary intake not to a supplement that is prepared with enhanced levels of materials. Applicant additionally contends that Sole's disclosure does not provide positive motivation to one of ordinary skill in the art to arrive at the claimed invention. Applicant argues that the use of vitamin E and C are not necessary and that alpha-lipoic acid is never mentioned. Finally, Sole does not specifically mention any specific neurodegenerative diseases, how they manifest and how the treatment affects the disease.

With respect to Weischer, Applicant argues that Weischer teaches a composition of alpha-lipoic acid and at least one vitamin for improved medication for at least 13 separate conditions, one of which is "neuroprotective". There is no further elaboration on the meaning "neuroprotection". Neither Sole nor Weischer provide enough disclosure to support a rejection for obviousness, especially for the method of use claims.

Said arguments have been considered but are not found to be persuasive.

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With respect to Applicant's argument that Sole does not mention specific neurodegenerative diseases, Applicant's claims do not require a specific neurodegenerative disease. Applicant's claims are drawn to methods of inhibiting mental deterioration or increasing mental capacity in an aged pet. In view of Sole, one of ordinary skill in the art would reasonably expect the phrase "functional deterioration" due to aging to encompass deterioration in mental capacity.

Moreover, Sole et al. do disclose a dietary supplement for administration to an animal such as dogs or cats, wherein the supplement may be used to treat a disease or state (functional deterioration) that is due to aging, wherein the supplement comprises L-carnitine, vitamin E, Vitamin C and Selenium. Please see the abstract; col. 11, lines 62-67; col. 12, lines 45-50; col. 13, lines 10-28; col. 14, line 67 to col. 15, line 3; col. 15, lines 39-40. Sole may not disclose alpha-lipoic acid, yet the Examiner again refers to Weischer et al. which discloses pharmaceutical compositions, for use in animals such as cats, comprising a combination of alpha-lipoic acid and Vitamin E for example, wherein the combination has detoxifying, immune-stimulating, cytoprotective effects. The Examiner maintains that it would have been obvious to one of ordinary skill in the art to modify the pet food compositions of Bernotavicz and Paluch to include the disclosed antioxidants of Sole for use in treating functional deterioration due to aging in dogs or cats because one of ordinary skill in the art would reasonably expect the resulting antioxidant-fortified pet food to be effective in providing the healthy as well as therapeutic advantages of the disclosed antioxidants. Such a modification would have been motivated by the reasoned expectation of producing an everyday pet food product that would serve to treat

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functional deterioration associated with aging in cats or dogs. Moreover, it would have been obvious to one of ordinary skill in the art to further modify the pet food product of Bernotavicz, Paluch and Sole to additionally include alpha-lipoic acid as taught by Weischer because one of ordinary skill in the art would reasonably expect the addition of alpha-lipoic acid to add detoxifying and cytoprotective effects to the pet food. In view of the advantageous and protective properties of the disclosed anti-oxidants, one of ordinary skill in the art would reasonably expect the antioxidant-fortified companion pet food product to increase the mental capacity of the aging animals.

Additionally, with respect to the rejection of claims 8, 9-11, 14, 16, 17, 18, 20-25, 28, 30-32, 34-36 under 35 USC 103(a) set forth in paragraph 19 of the office action mailed May 7, 2002, Applicant argues that Harper and Sole fail to disclose the claimed invention for reasons given above. In addressing the Packer reference, Applicant argues that the fact that alpha-lipoic acid might bring about improved memory performance in aged mice at a high dosage is not evidence that it will have a similar effect in dogs and cats because mice are substantially different from dogs and cats.

Said arguments have been considered but are not found to be persuasive.

The Sole and Harper references are maintained for reasons given above. With respect to Applicant's arguments concerning the Packer reference, it is the Examiner's position that the Packer reference strongly suggests to one of ordinary skill in the art that alpha-lipoic acid may be an effective antioxidant for treating neurodegenerative diseases. Absent evidence to the contrary,

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one of ordinary skill in the art, in view of the desirable results seen in aging mice, would reasonably expect alpha-lipoic acid and its antioxidant properties to be effective in improving memory performance in cats and dogs.

It is for these reasons that the rejections are maintained.

Conclusion

Claims 1-37 are rejected.

Claim 39 is withdrawn from consideration.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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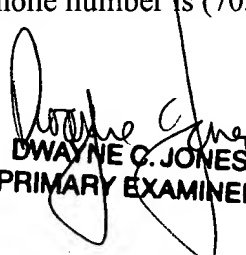
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

Dec. 31, 2002


DWAYNE C. JONES
PRIMARY EXAMINER